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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,085	05/09/2007	Valerie Frankard	4559-061539	7477

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
06/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,085	FRANKARD ET AL.	
	Examiner	Art Unit	
	STUART F. BAUM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21-25* is/are pending in the application.

4a) Of the above claim(s) *1,2,19 and 21-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-18 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *sequence search results (3)*.

DETAILED ACTION

1. Claims 1-19 and 21-25 are pending.

2. Applicant's election without traverse of Group II, including SEQ ID NO:1 and SEQ ID NO:2 in the reply filed on 3/4/2010 is acknowledged.

Claim 20 has been canceled.

Claims 1-2, 19 and 21-24 are withdrawn from consideration for being drawn to non-elected inventions.

3. Claims 3-18 and 25, including SEQ ID NO:1 and 2 are examined in the present office action.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See for example pages 13, 14, 16 and 31. See MPEP § 608.01.

Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from the amino acid sequence listed in Figure 3.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules

and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Claim Objection

6. Claims 3-11 are object to for being dependent on a non-elected invention. The Office notes that the claims have been amended to be dependent on a base claim that is not part of the elected Group II. The Office believes it is Applicants' intention that the amended claims be included in the elected Group II and therefore will be examined along with the elected claims belonging to Group II. Correction or clarification is requested. Dependent claims are included in the objection.

Claims 3 and 25 are objected to for being drawn to non-elected inventions. Correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

Claims 3 and 12 are indefinite in the recitation "seedy1 nucleic acid" or "seedy1 protein", respectively. The sole designation of a nucleic acid sequence or an amino acid sequence by "seedy1" is arbitrary and creates ambiguity in the claims. For example, the amino acid sequence

in this application could be designated by some other arbitrary means, or the assignment of said name could be arbitrarily changed to designate a different amino acid sequence or different nucleic acid sequence. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F .2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Amendment of the claim to refer to a specific SEQ ID NO would obviate this rejection. All subsequent recitations in which a nucleic acid sequence or amino acid sequence is identified as "seedy1" is also rejected.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 3-18 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for modifying the growth characteristics of a plant comprising modifying expression in a plant of a seedy1 nucleic acid and/or modifying the level and/or activity in a plant of a seedy1 protein comprising introducing and expressing in a plant a seedy1 nucleic acid/gene or a portion thereof, or sequences capable of hybridizing with the

seedy1 nucleic acid/gene, which nucleic acid encodes a seedy1 protein or a homologue, derivative or active fragment thereof wherein the nucleic acid is overexpressed; or a genetic construct comprising a seedy1 nucleic acid encoding a seedy1 protein, or method for the production of a transgenic plant comprising said nucleic acid or a plant transformed therewith; or an isolated seedy1 nucleic acid selected from the group consisting of a nucleic acid represented by SEQ ID NO:1, a nucleic acid encoding an amino acid sequence represented by SEQ ID NO:2, a nucleic acid encoding a homologue, derivative or active fragment thereof, a nucleic acid capable of hybridizing to any of the above nucleic acid sequences, a nucleic acid which is degenerate of any of the above, a nucleic acid which is an allelic variant or splice variant of any of the above, a nucleic acid encoding a protein having any of the percent identities listed in claim 25 or a portion of any of the above nucleic acid sequences.

The Office defines the term "represent" according to the Merriam Webster Online Dictionary, which defines "represent" to mean: to serve as a specimen, example or instance of, (Merriam Webster Online Dictionary. 2008, www.m-w.com/home.html; a copy of the definition is enclosed). The office interprets the recitation "a nucleic acid *represented* by SEQ ID NO:1" or "a nucleic acid encoding an amino acid sequence *represented* by SEQ ID NO:2"to read on more than just a single nucleic acid sequence.

Applicants isolated a cDNA clone from a synchronized tobacco BY2 cell culture line, and was cell cycle modulated, which was subsequently used to isolate a full-length cDNA of interest, namely the cDNA coding for the seedy1 protein of the present invention (CDS0689) (page 29, Example 1). Applicants disclose the seedy1 coding sequence (CDS0689) is set forth in SEQ ID NO:1 and encodes the protein of SEQ ID NO:2 (sequence listing).

The Applicants do not identify essential regions of seedy1 protein encoded by SEQ ID NO:1, nor do Applicants describe any polynucleotide sequences that hybridize to a seedy1 nucleic acid and encodes a protein or homologue, derivative or active fragment that when overexpressed in a plant modifies a growth characteristic.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a seedy1 protein falling within the scope of the claimed genus of polynucleotides which for example, hybridize to a seedy1 nucleic acid sequence and which encodes a seedy1 protein, homologue, derivative or active fragment and when overexpressed modifies a growth characteristic of a plant. Applicants only describe a single cDNA sequence of SEQ ID NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed

genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the seedy1 protein, it remains unclear what features identify a tobacco seedy1 protein. The prior art and the specification fail to disclose a correlation between the structure of the claimed sequences and the required function (see the enclosed Blast search result). Since the genus of seedy1 proteins has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

9. Claims 3-18 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule of SEQ ID NO:1 or a nucleic acid molecule encoding SEQ ID NO:2, wherein the nucleic acid molecule is operably linked to a promoter and plant transformation therewith and method for increasing plant biomass and seed yield comprising introducing said nucleic acid molecule into a plant, does not reasonably provide enablement for a nucleic acid molecule exhibiting less than 100% identity to SEQ ID NO:1 or encoding a protein exhibiting less than 100% identity to SEQ ID NO:2 and plant transformation therewith or any method comprising said nucleic acid molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists

a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a method for modifying the growth characteristics of a plant comprising modifying expression in a plant of a seedy1 nucleic acid and/or modifying the level and/or activity in a plant of a seedy1 protein comprising introducing and expressing in a plant a seedy1 nucleic acid/gene or a portion thereof, or sequences capable of hybridizing with the seedy1 nucleic acid/gene, which nucleic acid encodes a seedy1 protein or a homologue, derivative or active fragment thereof wherein the nucleic acid is overexpressed; or a genetic construct comprising a seedy1 nucleic acid encoding a seedy1 protein, or method for the production of a transgenic plant comprising said nucleic acid or a plant transformed therewith; or an isolated seedy1 nucleic acid selected from the group consisting of a nucleic acid represented by SEQ ID NO:1, a nucleic acid encoding an amino acid sequence represented by SEQ ID NO:2, a nucleic acid encoding a homologue, derivative or active fragment thereof, a nucleic acid capable of hybridizing to any of the above nucleic acid sequences, a nucleic acid which is degenerate of any of the above, a nucleic acid which is an allelic variant or splice variant of any of the above, a nucleic acid encoding a protein having any of the percent identities listed in claim 25 or a portion of any of the above nucleic acid sequences.

The Office defines the term "represent" according to the Merriam Webster Online Dictionary, which defines "represent" to mean: to serve as a specimen, example or instance of, (Merriam Webster Online Dictionary. 2008, www.m-w.com/home.html; a copy of the definition is enclosed). The office interprets the recitation "a nucleic acid *represented* by SEQ ID NO:1" or "a nucleic acid encoding an amino acid sequence *represented* by SEQ ID NO:2"to read on more than just a single nucleic acid sequence.

Applicants isolated a cDNA clone from a synchronized tobacco BY2 cell culture line, and was cell cycle modulated, which was subsequently used to isolate a full-length cDNA of interest, namely the cDNA coding for the seedy1 protein of the present invention (CDS0689) (page 29, Example 1). Applicants disclose the seedy1 coding sequence (CDS0689) is set forth in SEQ ID NO:1 and encodes protein of SEQ ID NO:2 (sequence listing). Applicants disclose rice plants transformed with the tobacco seedy1 nucleic acid molecule of SEQ ID NO:1 operably linked to a promoter exhibited increased biomass and increased number of filled seeds and increased seed weight (pages 32-34, Example 3).

Applicants have not provided examples or guidance for selecting a sequence out of the multitude of sequences that are encompassed by Applicants' broad claim language that gives the expected results when transformed into a plant. Transforming plants with heterologous genes that are involved in plant development produce unpredictable results. Kano-Murakami et al (1993, FEBS 334:365-368) teach introducing the *Oryza sativa* homeobox 1 (OSH1) gene into tobacco. OSH1 is a rice homologue of the *Knotted-1* homeobox gene from maize and would be encompassed by Applicant's broad claim language. Kano-Murakami et al teach transgenic tobacco plants comprising the OSH1 gene display a "range of phenotypes which include

abnormalities in leaf and petal shape as well as stem height and number" (page 365, right column, 1st paragraph).

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that encode a derivative or active fragment of any seedy1 protein or encode a protein exhibiting 21% sequence identical to SEQ ID NO:2 will encode a protein with the same activity as the protein encoded by SEQ ID NO:1. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

The Office contends that to satisfy the enablement requirement for claims drawn to nucleic acid sequences and plants and methods comprising said sequences, one of skill in the art must be able to generate nucleic acid sequences that fall within the scope of the claims and identify those sequences that are operable in Applicants' invention by assaying the sequences; all of which must not constitute undue trial and error experimentation. In the instant case, Applicants have not recited a functional limitation in the claims and have not provided as assay

which can be used to test putative sequences. Therefore, Applicants claims encompass a multitude of embodiments which are not enabled.

Applicants have not provided any teachings for one skilled in the art to predict and isolate nucleic acid sequences that encode a protein with the necessary activity to be operable in Applicants' invention. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences. Therefore, the instant specification fails to provide guidance for which amino acids of the protein encoded by SEQ ID NO:1 can be altered, the type of alteration, and which amino acids must not be changed, to maintain activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:1 as probes or by designing primers to undisclosed regions of SEQ ID NO:2 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce a plant exhibiting a modified growth characteristic.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 12-18 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Inze et al (2002, Pub. No.: US 2005/0221290 A1).

The claims are drawn to a genetic construct comprising a seedy1 nucleic acid encoding a seedy1 protein and one or more control sequences capable of regulating expression of the nucleic acid; plant or plant cell transformed with a construct, or method for the production of a transgenic plant comprising said nucleic acid or a plant transformed therewith; or an isolated seedy1 nucleic acid selected from the group consisting of a nucleic acid represented by SEQ ID NO:1, a nucleic acid encoding an amino acid sequence represented by SEQ ID NO:2, a nucleic acid encoding a homologue, derivative or active fragment thereof, a nucleic acid capable of hybridizing to any of the above nucleic acid sequences, a nucleic acid which is degenerate of any of the above, a nucleic acid which is an allelic variant or splice variant of any of the above, a nucleic acid encoding a protein having any of the percent identities listed in claim 25 or a portion of any of the above nucleic acid sequences.

The Office defines the term "represent" according to the Merriam Webster Online Dictionary, which defines "represent" to mean: to serve as a specimen, example or instance of, (Merriam Webster Online Dictionary. 2008, www.m-w.com/home.html; a copy of the definition is enclosed). The office interprets the recitation "a nucleic acid *represented* by SEQ ID NO:1"

or "a nucleic acid encoding an amino acid sequence *represented* by SEQ ID NO:2"to read on more than just a single nucleic acid sequence.

Inze et al disclose a nucleic acid sequence of SEQ ID NO:82 encoding a protein exhibiting 100% identity to Applicants' SEQ ID NO:2 and wherein SEQ ID NO:82 exhibits 100% identity to Applicants' SEQ ID NO:1 (page 14, Table 3; sequence search results included). Inze et al disclose that SEQ ID NO:82 is involved in the cell cycle (page 8, paragraph 96). Inze et al disclose a genetic construct comprising said nucleic acid operably linked to a control sequence (page 11, paragraphs 123-127). Inze et al disclose the invention is utilized in a variety of plants including for example, wheat (page 12, paragraph 139). The Office contends Applicants' method steps are the same as Inze et al. See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method, and as such, Inze et al anticipate the claimed invention.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
Stuart F. Baum Ph.D.
Primary Examiner
Art Unit 1638
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